REMARKS/ARGUMENTS

Claims 1-65 are pending in this application. Claims 1, 47-49, 51 and 65 have been amended to more clearly recite the invention. The claim amendments are all entirely supported by the application as filed and thus they raise no issue of new matter. Claim 64 has been canceled from the application without prejudice or disclaimer. Upon entry of this Amendment, claims 1-63 and 65, as amended, will be present in the application.

Claim Objections

Claim 47 is objected to due to a typographical error therein. The claim is, thus, amended to delete the word "has", such that it now reads, ". . . wherein said active peptide agent is amidated . . .". The amendment is believed to overcome the Examiner's objection, which should therefore be withdrawn.

Rejections Under 35 U.S.C. 112

Claims 48, 49 and 51 are rejected under 35 U.S.C. 112, Second Paragraph, for the reasons set forth in ¶2 on p. 2 of the Office Action.

In response, the subject claims have each been amended in a manner which is believed to overcome the grounds for rejection. These claim amendments are entirely supported by the application as filed, and thus they raise no issue of new matter. The Examiner is, therefore, respectfully requested to reconsider and withdraw the rejection thereof in light of the amendments made to the subject claims.

Rejections Under 35 U.S.C. 102

Claims 45-48, 50, 51, 54, 56 and 63 are rejected under 35 U.S.C. 102(b) over USP 5,912,014 to Stern, *et al.* (hereinafter, "Stern '014") for the reasons set forth in ¶6 on p. 4 of the Office Action. The rejection is respectfully traversed.

The rejected claims are directed to a method for enhancing the bioavailability of an orally delivered physiologically active peptide active agent (see, e.g., claim 45 which is the only rejected claim written in independent form). As recited in claim 45, the bioavailability is increased by a method which comprises: (A) amidating the peptide agent; and (B) orally administering the [amidated] peptide agent.

Whereas applicants will concede that Stern '014 discloses a method for enhancing the bioavailability of a salmon calcitonin that is delivered orally, and that such salmon calcitonin is a physiologically active peptide agent, in contrast to the claimed invention the reference discloses a completely different methodology than that recited in, e.g., claim 45, for increasing the bioavailability of the agent. That is, the patent teaches at, for example, col. 2, lines 19-32 of the subject reference that the method for enhancing the bioavailability of salmon calcitonin, comprises:

> selectively releasing said salmon calcitonin, together with at least one pH-lowering agent and at least one absorption enhancer, into a patient's intestine following passage of said salmon calcitonin, pH-lowering agent and absorption enhancer through the patient's mouth and stomach under protection of an enteric coating which substantially prevents contact between stomach proteases and said salmon calcitonin; wherein said pH-lowering compound is released by said vehicle into said intestine in an amount which, if added to 10 milliliters of 0.1M aqueous sodium bicarbonate solution, would be sufficient to lower pH of said solution to no higher than 5.5

Salmon calcitonin is naturally amidated. Stern '014 does not suggest further amidating salmon calcitonin, i.e, at a location that is not naturally amidated, for improving its bioavailability, as is herein claimed, or even that salmon calcitonin's natural amidation improves bioavailability. Instead, Stern '014 enhances bioavailability by the inclusion of additional agents, such as the pH-lowering agent, enhancer, etc. in the formulation with the peptide, rather than by making modifications to the molecular structure of the peptide (by amidating it at a location that is not naturally amidated), as is recited, for example, in present claim 1.

In summary, therefore, while the method of the Stern '014 Patent is directed to achieve a similar result to that of the present invention, it goes about achieving such result in a manner which is manifestly different from that recited in, e.g., independent claim 45. For a reference to anticipate a claim, the reference must disclose each of the elements recited within the claim. Since, however, the steps recited in independent claim 45 are neither taught nor even suggested by Stern '014, the Examiner is respectfully requested to reconsider and withdraw the rejection of that claim. Additionally, dependent claims 46-48, 50, 51, 54, 56 and 63 are believed to distinguish the invention over the cited reference for the same reason as independent claim 45. Therefore, the rejection of these dependent claims should also be withdrawn.

Claims 45-47, 50, 51, 54, 56, 61, 63 and 64 are rejected under 35 U.S.C. 102(b) over a different Stern reference, i.e, USP 6,086,918 to Stern, *et al.* (hereinafter, "Stern '918") for the reasons set forth in ¶7 on p. 4 of the Office Action. In response to the rejection, claim 64 is canceled without prejudice or disclaimer, thus rendering the rejection moot as to that claim. As to the remaining claims, i.e, nos. 45-47, 50, 51, 54, 56, 61 and 63, the rejection is respectfully traversed, for the reasons given below.

Of the claims rejected under 102(b) over Stern '918, only claim 45 is written in independent form. As pointed out in the discussion above concerning the rejection based on Stern '014, applicants' claim 45 is directed to a method for enhancing bioavailability of an orally delivered physiologically active peptide agent, wherein the method comprises: (1) amidating the peptide agent, and (2) orally administering the peptide agent.

Stern '918 discloses a methodology for enhancing the bioavailability of a range of peptide active agents which is essentially the same as that taught by Stern '014 (see description above), i.e., wherein the bioavailability is improved through the incorporation of additional agents into the formulation, rather than by making modifications to the molecular structure of the peptide as practiced in the presently claimed invention (see, e.g, claim 1). The method recited in applicants' claim 45 is, thus, again completely distinguishable from that disclosed by either Stern reference and, in particular, by Stern '918. This is due to the fact that, whereas the presently claimed method requires amidating the peptide agent, no such amidation step is either required or even suggested by Stern '918. That is, Stern '918 discloses a method for improving bioavailability of peptide active agents which entails the use, as described above in the discussion of Stern '014, of a pharmaceutical composition providing targeted release of the peptide to the intestine by virtue of an acid-resistant protective vehicle which transports components of the disclosed formulation through the stomach. The composition disclosed by the subject reference for achieving such an improvement in bioavailability includes an absorption enhancer and a sufficient amount of a pH-lowering agent to lower local intestinal pH, such that all of the components are released together into the intestine along with the peptide.

As can be seen from the above discussion, therefore, Stern '918, like Stern '014, neither teaches, nor even suggests, the invention recited in applicants' claim 45 and the Examiner is, therefore, respectfully requested to reconsider and withdraw the rejection of the subject claim. Additionally, dependent claims 46-47, 50, 51, 54, 56, 61 and 63 are believed to be

distinguishable for the same reasons as the independent claim and, thus it is requested that the rejection of these claims be withdrawn as well.

Claims 45-48, 50-54, 56, 61 and 63 are rejected under 35 U.S.C. 102(a) for the reasons set forth in ¶9 on pps. 5-6 of the Office Action as allegedly anticipated by WO 02/043767 of Unigene Laboratories, Inc. ("Unigene '767"), i.e, which is the owner by Assignment of the present application. This rejection is respectfully traversed for the reasons which follow. In addition, claim 64 is rejected under 35 U.S.C. 102(b) for anticipation over the same reference. The cancellation of claim 64, however, renders the rejection of that claim moot.

Turning, therefore, to the rejection of claims 45-48, 50-54, 56, 61 and 63, applicants note that claim 45 is the only one of those rejected claims which is written in independent form. The features of the invention recited in the subject claim are detailed above and that discussion is incorporated herein by reference. To briefly summarize, however, claim 45 is directed to a method of improving bioavailability of an orally delivered physiologically active peptide agent, which requires, *inter alia*, that the peptide agent be amidated.

Unigene '767 neither teaches nor even suggests the invention recited, e.g, in claim 45. That is, the reference contains no teaching to amidate a physiologically active peptide agent for the purpose of increasing or otherwise enhancing its bioavailability. In contrast to the invention of claim 45, Unigene '767 teaches one of ordinary skill in this art that bioavailability of physiologically active peptide agents is enhanced by: (A) linking the peptide active agent to a membrane translocator capable of being at least partially cleaved by a plasma protease; and (B) selectively releasing the peptide active agent linked to the membrane translocator, together with at least one pH-lowering agent and/or protease inhibitor into a patient's intestine following passage of the peptide active agent, pH-lowering agent and/or protease inhibitor through the patient's mouth and stomach under protection of an acid-resistant protective vehicle which substantially prevents contact between stomach proteases and the peptide agent. (See, e.g, p. 5, lines 17-32 of the publication). Despite the fact that, as noted in the Office Action (see ¶9), certain peptides such as salmon calcitonin and lhrf may be or are amidated, the reference contains no disclosure which a reasonable individual would construe as teaching a 'cause and effect' relationship between (1) amidating the peptide, and (2) enhancing its bioavailability upon oral administration. That is, the reference contains no teaching to amidate the peptide for the purpose of enhancing the bioavailability thereof.

For the reasons above, the Examiner is respectfully requested to reconsider and withdraw the §102(a) rejection of claim 45 based on Unigene '767. Moreover, the rejected claims which depend, directly or indirectly, from claim 45, i.e., nos. 46-48, 50-54, 56, 61 and 63, are also believed to distinguish the invention due to the fact that these claims contain all of the recitations found in claim 45. The Examiner is thus requested to also withdraw the rejection of the dependent claims.

Claims 1, 6 and 39 are rejected under 35 U.S.C. §102(b) over USP 5,157,021 to Balschmidt, *et al.* (hereinafter, "Balschmidt '021") for the reasons set forth in ¶11 on p. 7 of the Office Action. This rejection is respectfully traversed.

Balschmidt '021 discloses injectable pharmaceutical compositions comprising insulin wherein the carboxylic acid groups present in the side chains at residues A4, A17, B13 and B21 are amidated in order to achieve a long-lasting protracted acting insulin analog. The reference contains no teaching or suggestion, however, to convert the compositions described therein into a form which is suitable for oral delivery. In contrast, the pharmaceutical composition claimed by applicants is particularly adapted for oral delivery of the physiologically active peptide agent. In this regard, applicants note the Examiner's comment in ¶11 of the Office Action to the effect that, "an intended use limitation, e.g., 'for oral delivery' does not impart patentability to product claims where the product is otherwise anticipated by the prior art. In response, therefore, applicants have amended claim 1 (and, in addition, claim 65) to positively recite that the composition claimed therein is an oral pharmaceutical composition which is adapted for oral delivery of a physiologically active peptide agent. Thus, the claim(s), as amended, no longer recite an "intended use" for the composition. Instead, claim 1 now (as indicated above) positively recites that applicants' invention comprises an oral pharmaceutical composition, which is particularly adapted to permit oral delivery of the peptide agent. Since these features are in no way disclosed anywhere within the cited Balschmidt '021 reference, the subject reference thus does not disclose every element of applicants' invention as recited in claim 1. The Examiner is, therefore, respectfully requested to reconsider and withdraw the rejection of that claim under §102. Moreover, as claims 6 and 39 depend from claim 1 and thus contain all of the recitations of the subject claim, these dependent claims are believed to be distinguishable for the same reasons as claim 1. Thus, the rejection of claims 6 and 39 should also be withdrawn for the same reasons as that of claim 1.

Claims 1, 4, 5 and 37 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by USP 5,120,712 to Habener (hereinafter, "Habener '712") for the reasons set forth in ¶12 on pps. 7-8 of the Office Action. This rejection is respectfully traversed.

Habener '712 discloses and claims methods for treating diabetes, together with compositions comprised of fragments of glucagon-like peptide I (GLP-1) and functional derivatives (including amidated derivatives) thereof, that are useful in carrying out the claimed methods. The administration of the formulations disclosed and claimed in Habener '712 is discussed at col. 6, lines 31-48, wherein the reference teaches that they may be administered, "intravenously, intramuscularly or subcutaneously". In contrast to applicants' invention as presently recited, e.g., in claim 1, the subject reference includes no disclosure which would teach or suggest to one of ordinary skill in this art to include the compositions described therein in an oral pharmaceutical composition which is particularly adapted to orally deliver an active peptide agent to an individual requiring the same. As indicated above, applicants' claim 1 has now been amended to specifically recite these distinguishing features of the invention. Thus, as recited in claim 1, applicants' invention is not anticipated by Habener '712 since the subject reference does not disclose every element recited in, e.g., claim 1. The Examiner should, thus, reconsider and withdraw the rejection based on the subject reference. Moreover, claims 4, 5 and 37 all depend, directly or indirectly, upon claim 1 and thus contain all of the recitations found in that claim. Therefore, these claims are also believed to distinguish applicants' invention for the same reasons as claim 1 and the rejection thereof based on Habener '712 should also be withdrawn.

Claims 1, 4, 5, 40 and 41 are rejected under 35 U.S.C. §102(b) due to alleged anticipation by USP 6,110,892 to Barbier, *et al.* (hereinafter, "Barbier '892") for the reasons set forth in ¶13 on p. 8 of the Office Action. This rejection is respectfully traversed.

Barbier '892 is directed to the usage of parathyroid hormone analogues useful for the treatment of osteoporosis. In particular, the Examiner in the Office Action cites to col. 9, lines 25-46 of the reference (Example 4) which discloses the use for this purpose of the amidated parathyroid hormone fragment hPTH(1-31)NH_2. The cited portion of the specification, however, clearly teaches a formulation which is administered via injection (see, e.g., col. 9, lines 32, 39-44 and 55-59) and not via an oral route.

Contrasting Barbier '892 with the present invention, applicants note that rejected claims 4, 5, 40 and 41 all depend, directly or indirectly, from claim 1. As indicated above, claim 1 as amended now recites an oral pharmaceutical composition which is adapted for oral delivery of a

physiologically active peptide agent, wherein the active peptide is amidated at a location that is not naturally amidated. Since, as demonstrated above, the cited reference neither teaches nor suggests, as now claimed, an oral pharmaceutical composition that is adapted for oral delivery of the physiologically active peptide agent, applicants submit that the invention recited in claim 1 is neither taught nor even suggested by the reference. Thus, the Examiner is respectfully requested to reconsider and withdraw the rejection under §102. Moreover, the remaining rejected claims, i.e, nos 4, 5, 40 and 41 each contain all of the recitations found in claim 1 and, for that reason, those claims are believed to be distinguishable over Barbier '892 for the same reasons as claim 1. Thus, the Examiner should, additionally, withdraw the rejection of those claims as well.

Further to the above, claims 1, 4, 5, 40, 42, 45, 47, 58 and 60 are rejected under 35 U.S.C. §102(e) as allegedly anticipated by US Patent Application Publication 2004/0023882 of Peri, *et al.* ("Peri") for the reasons set forth in ¶14 on pps. 8-9 of the Office Action. This rejection is respectfully traversed.

The Peri reference is directed to PTH derivatives which are resistant to skin proteases, as well as to methods for their use. Representative examples of these derivatives are set forth at, for example ¶0067 of the reference. Further according to the reference [see ¶0068], the invention encompasses, *inter alia*, such hPTH sequences provided with amide protecting group(s) at the C-terminal end of the sequence.

The rejected claims may be divided into two groups, i.e., (1) those directed to a pharmaceutical composition (nos. 1, 4, 5, 40 and 42); and (2) those directed to a method for enhancing bioavailability of an orally delivered physiologically active peptide agent (nos. 45, 47 and 58). Turning to a discussion of the first claim group, i.e., directed to a composition, applicants note that the C-terminal end of the hPTH sequence is a location where amidation naturally occurs and thus the reference does not meet the requirement of claim 1, i.e, wherein the active peptide is amidated at a location that is not naturally amidated. Claim 1 is thus believed to distinguish over the reference, as are claims 4, 5, 40 and 42, which depend directly or indirectly on claim 1 and thus include every feature recited in the independent claim. The Examiner is, therefore, respectfully requested to reconsider and withdraw the rejection of claims 1, 4, 5, 40 and 42.

Turning next to the method claims rejected under 102(e) over the Peri reference, applicants submit that the invention as recited, e.g., in independent claim 45 is, as noted above, a method for enhancing bioavailability of an orally delivered physiologically active peptide agent

which method comprises, *inter alia*, amidating the peptide agent. While applicants will concede that the cited reference does disclose amidated peptide agents, it is submitted that the reference, however, contains no teaching or suggestion that it is likely, or indeed even possible, that the bioavailability of peptide agents can be improved by amidating these agents. Since the reference thus does not teach every element of the claimed invention as recited in claim 45, applicants respectfully request the Examiner to reconsider and withdraw the §102(e) rejection of the subject claim. Moreover, as claims 47, 58 and 60 each depend, directly or indirectly, upon claim 45 and thus contain all of the limitations in that claim, the dependent claims are believed to be distinguishable over the cited reference for the same reasons as claim 45. Thus, the Examiner should also withdraw the rejection of those claims.

Rejections Under 35 U.S.C. §103

Claims 1-8, 12-47, 49-51, 54-60, 62, 63 and 65 are rejected under 35 U.S.C. §103(a) for alleged 'obviousness' over Stern '918 as applied against claims 45-47, 50, 51, 54, 56, 61, 63 and 64, and further in view of Habener '712, Balschmidt '021, Barbier '892, European Patent Application No. 878,201 ("EP '201") or USP 4,804,742 to Neiss, *et al.* (hereinafter, "Neiss '472") for the reasons set forth in ¶8 on pps. 4-5 of the Office Action. This rejection is respectfully traversed.

The Stern '918 patent is discussed above in detail and those comments are specifically incorporated by reference into this discussion. Contrasting the features recited in the independent claims encompassed by the rejection, i.e, nos. 1, 45 and 65, with the disclosure of Stern '918, applicants note the following. As to claim 1, Stern '918, at a minimum, does not teach or suggest to amidate an active peptide at a location that is not naturally amidated. With regard to claim 45, the subject reference does not teach a method of enhancing the bioavailability of a peptide agent by amidating the agent and administering the amidated agent. Finally, turning to claim 65, while parathyroid hormones, in general, are disclosed in Stern '918, there is no specific disclosure concerning PTH[1-34]OH. In applicants' view, the only means by which the disclosure in Stern '918 could be construed as disclosing the specific parathyroid hormone fragment now recited in claim 65 of the present case, is via the prohibited practice of making a hindsight reconstruction of the presently claimed invention based upon the teachings provided by applicants in their specification.

Turning next to the so-called 'secondary references' that are combined, in the alternative, with Stern '918 to reject the claims, applicants submit that the reasons why Habener '712,

Balschmidt '021 and Barbier '892 fail to teach or suggest the present invention are discussed above and those remarks are specifically incorporated by reference into this discussion. The Examiner is, thus, respectfully requested to reconsider and withdraw the rejections based on Stern '918 + Habener '712; Stern '918 + Balschmidt '021; and Stern '918 + Barbier '892.

As to the remaining secondary references not previously discussed herein, i.e., EP '201 and Neiss '742, applicants note the following. According to the Office Action, EP '201 is cited due to its teaching of the human parathyroid hormone derivative hPTH[1-34]NH_2. In general, EP '201 is directed to agents for preventing and treating thrombocytopenia. One preferred agent includes the 1-34 amidated PTH fragment as the active ingredient. The crucial area of distinction, however, lies in the fact that the subject reference does not teach to orally administer the formulations described therein, in contrast to Stern '918, which is directed to administration of active peptide agents via an oral route. In the paragraph bridging cols 3-4 of the EP '201 reference, it states:

> A typical dosage form for the pharmaceutical drugs of the invention is injections (e.g., liquid preparations and lyophilized preparations) that are produced by ordinary pharmaceutical formulation procedures applicable to peptides; also useful are dosage forms that are intended to [be] show local and delayed actions, as by inclusion within microcapsules or incorporation in sheets of gel.

Further to the above, the reference contains a number of Examples, none of which discuss orally administering the peptide agent. Applicants submit, therefore, that the references contain no disclosure which would suggest their combination, as one reference (Stern '918) discloses oral administration , whereas the EP reference teaches to administer the peptides via injection. The Examiner states in the Office Action that it would have been 'obvious' to use the specific peptides of, e.g., EP '201 in the oral formulation according to Stern '918 because, "oral administration is easier for the patient." This represents, to applicants, a 'classic' example of hindsight reconstruction wherein, although EP '201 nowhere teaches or suggests to utilize oral administration, the Examiner alleges that it would require no inventive step to ignore the reference's teaching to inject the peptide and substitute, instead, a totally different mode of administration, i.e., oral administration, for such injection technique. In light of the arguments presented above, therefore, the Examiner is thus respectfully requested to reconsider and withdraw the rejection under 103 based on Stern '918 + EP '201.

Turning next to the patent to Neiss et al. (Neiss '742), the subject reference describes and claims amide analogs of calcitonin. As regards the present invention, claim 1 (for example) recites (*inter alia*) an oral pharmaceutical composition wherein an active peptide is amidated at a location that is not naturally amidated. In contrast the Neiss '742 reference refers to "amide" analogs of calcitonin. While the terms "amidated" and "amide" may look similar, they do not have the same meaning. More particularly, "amidation" refers to "the posttranslational conversion of C-terminal glycine-extended peptides to C-terminal alpha-amidated peptide" [see, for example, http://crfb.univ-mrs.fr/aniseed/GO-definition.php?id=GO:0001519]. In contrast, however, the term "amide" as used in the subject reference (Neiss '742) refers to acylated derivatives, "at the peptide positions having a lysine or arginine, or at the cysteine at position one" (see col. 3, lines 15-17 of the cited reference). It is, therefore, apparent that the composition of the presently claimed invention comprises an active peptide agent that is modified in a manner which significantly differs from the modifications taught by Neiss '742. Thus the present invention, as recited in claim 1(and those claims which depend therefrom) is distinguishable over Neiss '742 taken alone or in combination with Stern '918.

Turning next to applicants' (method) claim 45, there is no disclosure anywhere within the Neiss '742 reference of a method for enhancing the bioavailability of the calcitonin amide analogs taught therein. Rather, the reference is directed, in particular, to the formation of analogs having biological activity and, preferably, an extended duration of activity. Thus, not only is the reference not directed to disclosing how to improve bioavailability, it lacks any teaching that peptide active agents should be amidated for the express purpose of improving such bioavailability. Finally, as to claim 65, the reference provides no additional disclosure to that contained in Stern '918 which would suggest the pharmaceutical composition recited by the subject claim to one having ordinary skill in this field of art.

The Examiner is, therefore, respectfully requested to reconsider and withdraw the rejection of independent claims 1, 45 and 65 under §103(a) over the cited references. Moreover, the remaining rejected claims each depend, directly or indirectly, on one of the above independent claims and, as these dependent claims include all of the limitations found in the respective independent claims, the dependent claims are believed to be distinguishable for the same reasons as the independent claims. Thus, the Examiner should additionally withdraw the §103(a) rejection of those claims as well.

In addition to the rejections discussed above, claims 1-47, 49-60, 62, 63 and 65 of the application are rejected under 35 U.S.C. §103(a) over Unigene '767 as applied above in the §102 (a) rejection of claims 45-48, 50-54, 56, 61 and 63, and further in view of Habener '712, Balschmidt '021, Barbier '892, EP '201 or Neiss '742 for the reasons set forth in ¶10 on pps. 6-7 of the Office Action. The rejection is respectfully traversed.

The Unigene '767 reference is particularly well-known to the applicants as it is owned by the owner of the present application and it names as inventors two of the same individuals who are co-inventors of the present application. The reference, and particularly the features which distinguish it from applicants' present invention, are discussed above with regard to the §102(a) rejection of claims 45-48, 50-54, 56, 61 and 63. Those remarks are specifically incorporated by reference into this discussion and, thus, need not be repeated here. Suffice to say, however, that the subject reference does not teach to amidate an active peptide at a location that is not naturally amidated, and thus does not meet the requirements of claim 1; and it does not disclose a method for enhancing the bioavailability of an active peptide by, *inter alia*, amidating the peptide and then administering the amidated peptide. Thus, Unigene '767 also does not meet the requirements of claim 45. Finally, as to claim 65, the reference contains no specific teaching to choose, as the active peptide, the PTH[1-34]OH, i.e., the 1-34 "free acid" fragment, specifically recited for use in applicants' claim 65. For at least the reasons above, therefore, the independent claims of the present application are readily distinguishable over Unigene '767. Thus the claims depending from claims 1 and 45 (claim 65 has no dependent claims) are also distinguishable over the Unigene '767 reference since they contain all of the recitations found in the corresponding independent claim.

Further to the above, each of the secondary references, i.e, Habener '712, Balschmidt '021, Barbier '892, EP '201 and Neiss '742, which are combined with Unigene '767 to reject applicants' claims, is also discussed above in detail and this discussion is specifically incorporated herein by reference. Based on the descriptions provided concerning the content of the references (or, in certain cases, their lack of content regarding specific elements of applicants' presently claimed invention) and pursuant to the arguments provided with regard to how the present invention is distinct from the references, it is applicants' position that none of the cited secondary references, whether viewed alone or in combination with Unigene '767, teach or would even suggest the invention recited in any of applicants' independent claims. Based on

this, the Examiner is respectfully requested to reconsider and withdraw the §103(a) rejection of claims 1-47, 49-60, 62, 63 and 65.

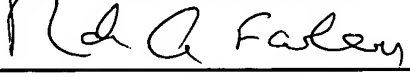
Summary

For all of the reasons above, applicants submit that this Amendment is believed to overcome all of the grounds for objection and rejection cited by the Examiner. Thus, the Examiner is respectfully requested to reconsider and withdraw the subject objections and rejections.

If the Examiner believes that the prosecution of this case would be advanced through an interview, he is respectfully invited to telephone applicants' representative at the number below in order to arrange for such an interview.

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on: July 10, 2006

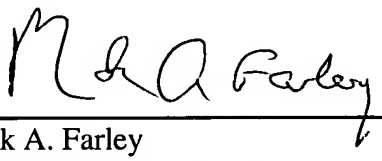
Mark A. Farley
Name of applicant, assignee or Registered Representative



Signature

July 10, 2006
Date of Signature

Respectfully submitted,



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